

APR 24 1997

A Summary of Safety and Effectiveness Information

Name of Device: Unitron Industries, Sound F/X Programmable

Type of Device: In-The-Ear Programmable Hearing Aid. Substantially equivalent to other In-The-Ear Programmable hearing aids.

Intended Use: To amplify and transmit sound via air conduction to the ear.

Features: Five programmable parameters: Low-channel Gain, High-channel Gain, Cross-over Frequency, Threshold Kneepoint, Power.

Two channels with wide dynamic range compression circuitry independently adjustable for each channel.

Twin average compression detectors.

Class D circuitry for excellent battery life.

Assembly: Assembled from standard components that are used by Unitron and other hearing aid manufacturers.

Technical Characteristics: Technical Specifications comply with ANSI Standard S 3.22-1987.

Controls: Volume Control, similar to other devices.

Power: Standard hearing aid battery - size 13, 312 or 10A.

A user's manual and other information is supplied with each hearing aid.